

## REMARKS

The present application relates to attenuation of pathangiogenic conditions by administering Group B  $\beta$ -hemolytic *Streptococci* toxin receptors or immunogenic fragments thereof, to compositions comprising such fragments, as well as to methods of producing the compositions. Claims 1, 4-16, 29-38, and 40-56 were pending. In the present Amendment and Response, applicant cancel Claims 49-54 and requests entry of the amendments of Claims 1, 30, and 55. Amendments do not introduce any new matter. Claims 1, 4-16, 29-38, 40-48 and 55-56 will be pending upon entry of the amendments. Based on the amendments and the following remarks, applicant respectfully requests reconsideration and allowance of the claims under prosecution.

### *Claim Rejections under 35 U.S.C. § 112, first paragraph*

The Examiner maintains the rejection of Claims 1, 4-16, 29-38, 40-48, 55, and 56 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner maintains that the mouse *in vivo* experimental data provided in the specification and showing tumor suppression in mice is not enabling for the claimed compositions and methods.

### Claims 1, 4-16, 30-38, 40-48, 55, and 56

In an effort to facilitate prosecution, applicant requests entry of the amendments of Claims 1, 30 and 55. Applicant respectfully thanks the Examiner for the telephone conference in November, 2004, and discussion of possible claim amendments. Support for the amendments is provided throughout the application as originally filed, for example, but not limited by, original Claim 30. Applicant respectfully asserts that the amendments overcome the rejection of Claims 1, 4-16, 30-38, 40-48, 55, and 56 under 35 U.S.C. § 112, first paragraph, and renders them allowable.

Upon entry of the amendments as requested by applicant, Claims 1, 30 and 55 will recite attenuating or attenuation of a pathoangiogenic condition. Applicant respectfully

asserts that the disclosure of the present application enables one of ordinary skill in the art in the field of cancer studies to make and use, without undue experimentation, the compositions recited in Claims 1, 4-16, 30-38, 40-48, 55, and 56. Particularly, the disclosure of the present application enables one of ordinary skill in the art in the field of cancer studies, without undue experimentation, to obtain compositions comprising one or more Group B  $\beta$ -hemolytic *Streptococci* toxin receptors or immunogenic fragments thereof, wherein the GBS toxin receptor comprises HP59 and SP55, and to use the compositions to induce or maintain an immune response in a mammal to at least one of the Group B  $\beta$ -hemolytic *Streptococci* toxin receptors, and to prevent or attenuate development of pathoangiogenic conditions, including cancer, in a mammal. For example, Example 6 of the present application shows that, in mouse models, immunization by compositions comprising immunogenic fragments of Group B  $\beta$ -hemolytic *Streptococci* toxin receptors prevents intravenously injected melanoma cells from establishing lethal metastases in the lungs.

One of ordinary skill in the art in the field of the invention, would consider mouse models used in the present application as reasonably correlating with the human pathoangiogenic conditions, such as cancer. Those of ordinary skill in the art in the field of cancer studies consider mouse models reasonably predictive of the therapeutic utility of compositions and methods for preventing or attenuating pathoangiogenic conditions, such as cancer. In the Office Action mailed July 26, 2004, the Examiner stated that the publication by Fu *et al.* "Identification of a Novel Membrane Protein, HP59, with Therapeutic Potential as a Target of Tumor Angiogenesis" *Clinical Cancer Research*, V. 7, pp. 4182-4194, (2001) (hereinafter *Fu*) showed that the applicant's immunogenic peptides were effective in attenuating tumors, not in preventing cancer. Applicant respectfully asserts that *Fu* shows that the compositions claimed in the present application can be used to prevent or attenuate pathoangiogenic conditions, such as cancer. In support of his position, applicant submits herewith a declaration by one of ordinary skill in the art under 37 C.F.R. §1.132.

In view of the foregoing, applicant respectfully assert that amendments overcome the rejection of Claims 1, 4-16, 30-38, 40-48, 55, and 56 under 35 U.S.C. § 112, first paragraph.

Applicant respectfully requests entry of the amendments of Claims 1, 30 and 55, and withdrawal of the rejection of Claims 1, 4-16, 30-38, 40-48, 55, and 56 under 35 U.S.C. § 112, first paragraph.

#### Claim 29

Applicant respectfully traverses the rejection of Claim 29, under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully asserts that new reasons are presented in this Response to convince the Examiner that Claim 29 is, in fact, allowable. Therefore, Applicant respectfully requests that at least the finality of the rejection of Claim 29 be withdrawn in accordance with MPEP 706.07(e) (third paragraph). Applicant respectfully asserts that the disclosure of the present application is enabling for the composition as claimed in Claim 29, and requests withdrawal of the rejection of Claim 29 under 35 U.S.C. § 112, first paragraph.

The Examiner maintains that the mouse *in vivo* experimental data provided in the specification and showing tumor suppression in mice is not enabling for the composition claimed in Claim 29. MPEP 2164.01(c) provides:

“...[W]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use.”

Applicant respectfully brings to the Examiner's attention that Claim 29 recites a composition comprising one or more Group B  $\beta$ -hemolytic *Streptococci* toxin receptors or immunogenic fragments thereof, wherein the GBS toxin receptor comprises HP59 and SP55. Claim 29 is not limited by a use of the recited composition. Applicant respectfully asserts, and discusses in the previous section of this Response, that the disclosure of the present application enables one of ordinary skill in the art in the field of cancer studies, without undue experimentation, to obtain compositions comprising one or more Group B  $\beta$ -hemolytic *Streptococci* toxin receptors or immunogenic fragments thereof, wherein the GBS

toxin receptor comprises HP59 and SP55, and to use the compositions to induce or maintain an immune response in a mammal to at least one of the Group B  $\beta$ -hemolytic *Streptococci* toxin receptors, and to prevent or attenuate development of pathoangiogenic conditions, including cancer, in a mammal. Therefore, the disclosure of the present application enables a use of the composition recited in Claim 29 and precludes a rejection for nonenablement on based on how to use.

Furthermore, the Examiner previously stated in the Office Action mailed July 16, 2003, that the specification of the present application is reasonably enabling for a composition for attenuating tumor burden in mice challenged with melanoma or Lewis lung tumor cells and reasonably enabling for a method for protecting against melanoma in mice. While disagreeing with the Examiner's position, applicant respectfully asserts that the composition recited in Claim 29 is enabled for at least the reasons stated by the Examiner.

In view of the foregoing, applicant respectfully asserts that a rejection of Claim 29 for nonenablement based on how to use is improper. Applicant requests withdrawal of the finality of the Office Action, at least with respect to Claim 29, and withdrawal of the rejection of Claim 29 under 35 U.S.C. § 112, first paragraph.

In view of the foregoing, Applicant respectfully asserts that the disclosure of the present application is enabling and contains working examples commensurate in scope with the claims, as pending upon entry of the amendments. The specification provides sufficient guidance to a skilled artisan to make and use the claimed invention without undue amount of experimentation. Applicant respectfully requests that the rejection of Claims 1, 4-16, 29-38, 40-48, 55, and 56 under 35 U.S.C. § 112, first paragraph, be withdrawn.

## CONCLUSION

Applicant is of the opinion that the Office Action has been completely responded to and that the application is now in condition for allowance. Such action is respectfully requested. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned at (404) 815-6102 is respectfully solicited.

Respectfully submitted,



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